EXHIBIT B

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Sherry Fox, et al. v. Ethicon, Inc.., et al No. 2:12-cv-00878	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Tracey & Fox Law Firm to give medical opinions related to Sherry Fox. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these

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devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including autologous tissue based slings, biological graft-based slings, and periurethral bulking procedures.. I have attended training provided by Ethicon, Inc. including training on TVT devices. Additionally, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Sherry Fox:

- Ft. Duncan Regional Medical Center;
- Dimmit County Memorial Hospital;
- Pasteur Plaza Surgery Center;
- Women in Partner's ObGyn;
- Praful Singh, MD;
- The Women's Clinic; and
- Photographs of Explanted Mesh taken by Steelgate

In addition I have reviewed the following medical literature and other TVM related documents and have relied, in part, on the documents below in addition to my medical and clinical experience in forming my opinions:

- AMA 8.08

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- TVT Instructions for Use
- C.G. Nilsson et al "Seventeen years' follow-up of the tension free vaginal tape procedure for female stress urinary incontinence." Int. Urogynecol. J. (2013) 24:1265-69
- P. Hilton "A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in treatment of genuine stress incontinence" British Journal of Obst. & Gynecol (February 1989, Vol 96, pp. 213-220
- H. Enzelsberger et. al "Comparison of Burch and Lyodura Sling Procedures for Repair of Unsucessful Incontinence Surgery" Obstet & Gynecol, Vol 88, No. 2, August 1996
- A.S. Arunkalaivanan et al "Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire based study" Int. Urogynecol J (2003), 14: 17-23
- K. Guerrero et al "A randomized controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up" Int. Urogynecol J (2007) 18:1263-1270
- B. Welk et al, "Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontience" JAMA Surgery, Published Online September 9, 2015.
- E. Petri et al., "Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification" Eur. J. of Obstet. & Gynecol. and Reprod. Bio. 165 (2010) 347-351
- B. Klosterhalfen et al., "Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair" Biomaterials (1998) 2235-46
- J. Anger et al., "Complications of Sling Surgery Among Female Medical Beneficiaries" Obstet. & Gynecol. Vol. 109, No. 3 (March 2007)
- P. Moalli et al, "Tensile Properties of five commonly used mid-urethral sling relative to the TVT" Int. Urogynecol J (2008) 19:655-663

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- A. Clave et al, "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants" Int. Urogynecol J (2010) 21:261-270
- O. Chinthakanan et al., "Mesh Removal Following Sling/Mesh Placement: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-139-40
- O. Chinthakanan et al, "Indication and Surgical Treatment of MidUrethral Sling Complications: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-142-43
- E. Petri et al., "Comparison of late complications in retropubic and transobturator slings in stress urinary incontinence" Int. Urogynecol. J. (2012) 23:321-325
- S. Abbott et al., "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study" American J. of Obset. & Gynecol (February 2014) 163.e1-8.
- G. Agnew et al, "Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence" Int. Urogynecol J. (2014) 25:235-239
- J. Duckett et al, "Pain after suburethral sling insertion for urinary stress incontinence" Int. Urogynecol J. (2013) 24:195-201
- C. Skala et al., "The IUGA/ICS classification of complications of prosthesis and graft insertion" Int. Urogynecol J (2011) 22:1429-1435
- K. Svabik et al., "Ultrasound appearances after mesh implantation – evidence of mesh contraction or folding?" Int. Urogynecol J. (2011) 22:529-533
- A. Rogowski et al., "Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair" Int. Urogynecol. J. (2013) 24:2087-2092

In addition, I have reviewed the following depositions:

- Deposition of Sherry Fox;
- Deposition of George Warner, DO;
- Deposition of Michelle Villa-Olvera, MD; and
- Deposition of Rashel Haverkorn, MD

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I have also personally interviewed and examined Sherry Fox on December 4th, 2015 as part of an independent medical exam to assist in the formulation of my opinions.

Clinical History

- On September 20, 2002, Mrs. Fox presented at the Women's Clinic. She complained of losing urine for the previous year when jumping or sneezing. Stress Incontinence was discussed and Mrs. Fox was referred for a possible TVT.[1] Her medical history prior to this visit is unremarkable.

- On December 3, 2002, Mrs. Fox executed a consent form acknowledging the following may occur in connection with the procedure: infection; bleeding; urinary retention; bladder perforation; continued incontinence.[2]

- On December 5, 2002, Dr. Warner performed the TVT tape insertion with cystoscopy. Dr. Warner began the procedure with IV sedation and vaginal prep. He infiltrated the retrovesical and perivesical spaces with a curved 22 spinal needle. He then infiltrated and incised the suburethral area with a one inch incision. After draining the bladder, he passed the left side of the tape. Cystoscopy was negative. He then performed a similar passing of the tape on the right side. Dr. Warner questioned bladder peforation and noted leakage of water. He attempted to back out the right arm of the TVT but was unable to. He incised the tape and removed the entire device. He then re-initiated the TVT procedure starting on the right side. Cystoscopy was negative. The patient was allowed to become more awake and the bladder was filled with 250-300cc of fluid. Mrs. Fox was asked to cough intraoperatively. This did not result in leakage. The sheathing was removed and the tape was cut in the suprapubic area. The vaginal incision was closed with chromic suture. Vaginal packing was applied and Mrs. Fox was kept in the hospital overnight.[3]

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[1] Women's Clinic 0002
[2] FOX_FDRMC_MDR00050
[3] FOX_FDRMC_MDR0017

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- On July 14, 2003, Mrs. Fox saw Dr. Villa-Olvera. Dr. Villa-Olvera noted the SUI had resolved following the surgery. There is no mention of erosion or atrophy at this visit.[4]

- On February 9, 2004 Mrs. Fox saw Dr. Villa-Olvera. She complained of pain in the vaginal area at the introitis and discomfort on penetration. Dr. Villa-Olvera noted a small area of tenderness at the right fourchette and white discharge. She assessed Mrs. Fox as having a yeast infection and prescribed Diflucan.[5] There is no mention of erosion or atrophy noted at this visit.

- On March 2, 2004, Mrs. Fox saw Dr. Villa-Olvera who noted pinpoint tenderness to the right of introitis. Dr. Villa-Olvera performed a punch biopsy of the right fourchette and assessed Mrs. Fox as having possible vulvular vestibulitis.[6] There is no mention of erosion or atrophy at this visit.

- A March 2, 2004, tissue examination of right perineal skin was noted to be consistent with early stage lichen sclerosis.[7]

- On April 13, 2004, Mrs. Fox saw Dr. Villa-Olvera. She was diagnosed with lichen sclerosis and prescribed Clobetasol. There is no mention of erosion or atrophy at this visit.[8]

- On August 24, 2004, Mrs. Fox saw Dr. Villa-Olvera. The previous pain was noted to be gone. Physical exam revealed lichen sclerosis to the left labia and improved vulvular vestibulitis. There is no mention of erosion or atrophy at this visit.[9]

- On October 3, 2005, Mrs. Fox saw Dr. Villa-Olvera. She complained of vaginal pain only with intercourse that was "like a sticker." Dr. Villa-Olvera noted lichen sclerosis at the introitis and noted the vagina to be non-tender. Dr. Villa-Olvera assessed that the vaginal pain was more likely related to a suture and not likely related to

[4] FOX_WPOBG_MDR00130
[5] FOX_WPOBG_MDR00131
[6] FOX_WPOBG_MDR00131
[7] FOX_WPOBG_MDR00146
[8] FOX_WPOBG_MDR00133
[9] FOX_WPOBG_MDR00132

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vestibulitis. Mrs. Fox reported the pain as tolerable. There is no mention of erosion or atrophy at this visit.[10]

- On February 29, 2008, Mrs. Fox saw Dr. Villa-Olvera for an annual exam. She reported no problems with intercourse. Her physical exam was unremarkable. There was no mention of erosion or atrophy at this visit.[11]

- On April 21, 2009, Mrs. Fox saw Dr. Villa-Olvera for an annual exam. She reported no problems with intercourse. Her physical exam was unremarkable. There is no mention of erosion or atrophy at this visit.[12]

- On August 10, 2010, Mrs. Fox saw Dr. Villa-Olvera for her annual exam. She reported no problems with intercourse. She did report vasomotor symptoms. Her review of symptoms was positive for painful periods and irregular bleeding. Her physical exam was unremarkable. There is no mention of erosion or atrophy at this visit.[13]

- On January 27, 2012, Mrs. Fox saw Dr. Villa-Olvera for an annual exam. She reported moderate dyspareunia for a period of months. Physical examination revealed a 1 cm erosion of the edge of the TVT through the vaginal mucosa to the right of the urethra. No atrophic changes are noted at this visit. Mrs. Fox was prescribed estrogen cream and the need for a potential referral was discussed.[14]

- On February 24, 2012, Mrs. Fox saw Dr. Villa-Olvera for a follow up on her mesh extrusion. Mrs. Fox described having burning vaginal pain brought on by sexual intercourse. She reported that the estrogen cream was ineffective in treating her symptoms. Physical exam revealed a 2 cm edge of the TVT palpable under the right pubis. No atrophic changes were noted at this visit. Mrs. Fox was referred to Dr. Haverkorn.[15]

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[10] FOX_WPOBG_MDR00134
[11] FOXS_WPOBG_MDR00180-183
[12] FOXS_WPOBG_MDR00202-205.
[13] FOXS_WPOBG_MDR00210-213
[14] FOXS_WPOBG_MDR221-224
[15] FOXS_WPOBG_MDR225-227

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- On March 8, 2012, Mrs. Fox saw Dr. Haverkorn for mesh sling complications. Physical exam revealed a 1 cm erosion on the right side lateral to her urethra. Tenderness was noted over the extrusion. Her physical exam was otherwise unremarkable. No atrophy was noted. Dr. Haverkorn's plan was to proceed with sling excision and possible urethral reconstruction.[16]

- On March 21, 2012, Mrs. Fox underwent excision of vaginal mesh and cystoscopy for treatment of vaginal mesh extrusion. The 1 cm area of extrusion was located in the area of the right vaginal fornix. The mesh was removed from the suburethral area from the right fornix to the left fornix. The mesh in the area of the right fornix was noted to be taut. The left side of the sling was noted to be incorporated into the urethral wall. The midurethral portion of the TVT was removed in two pieces. Attention was then shifted to the area of erosion at the right fornix. The sling was surgically released from the surrounding scar tissue and removed. The wound was re-approximated and vaginal packing placed.[17]

- On March 30, 2012, Mrs. Fox saw Dr. Haverkorn for a follow up after surgery. She had a Foley in place. Other than minimal vaginal bleeding and several bladder spasms, she voiced no other major complaints. A voiding trial was performed and Mrs. Fox passed her voiding trial.[18]

- On April 14, 2012, Mrs. Fox saw Dr. Villa-Olvera with a chief complaint of vulvar irritation. Physical exam revealed excoriations to the external genitalia and perineum. No atrophic changes are noted. Dr. Villa-Olvera assessed Mrs. Fox as having pruritus. Dr. Villa-Olvera prescribed Diflucan and Nystatin-triamcinolone.

- On May 10, 2012, Mrs. Fox saw Dr. Michael Owolabi for complaints of vulvular and vaginal itching. He performed a pelvic exam which revealed inflamed vestibular structures including the clitoris, labia minora and labia majora. Dr. Owolabi noted Wickham striae surrounding inflamed erosive areas and progressive introital stenosis.[19]

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[16] FOXS_URSA_MDR0011-16.
[17] FOXS_URSA_MRD0061-63
[18] FOXS_URSA_MDR00017-020
[19] FOXS_WOMCL_MDR0024-25

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- On June 22, 2012, Mrs. Fox saw Dr. Haverkorn for follow-up. Her symptoms were noted to have improved since her last visit. She presented with complaints of vulvar irritation and vaginal bleeding. Physical exam revealed atropic vaginitis, a well healed vaginal wall excision, no mesh, and old brownish blood near the apex. Mrs. Fox was restarted on estrogen.[20]

- On September 17, 2012, Mrs. Fox saw Dr. Villa-Olvera secondary to abnormal uterine bleeding. Mrs. Fox complained of continued pain at the mesh site with intercourse. A physical exam noted evidence of old black bleeding present. There is no mention of erosion or atrophy at this visit. An ultrasound evaluation was obtained which revealed fibroids/leiomyoma of the uterus.[21]

- On December 11, 2012, Mrs. Fox saw Dr. Haverkorn. She complained of SUI with cough/sneeze and persistent dyspareunia, better after surgery. Physical exam noted well estrogenized vaginal mucosa and mild urethral hypermobility. Physical exam did not note any mesh extrusion.[22]

- On April 16, 2013, Mrs. Fox saw Dr. Villa-Olvera for an annual exam. She reported dyspareunia and insertional pain. Her physical exam was unremarkable. There is no atrophy or erosion noted.[23]

- On April 17, 2014, Mrs. Fox saw Dr. Villa-Olvera for an annual exam. She reported dyspareunia and no vasomotor symptoms. Other than mild bleeding at the cervix, her physical exam was unremarkable. There is no atrophy or erosion noted.[24]

- On April 17, 2014, Mrs. Fox saw Dr. Haverkorn. Mrs. Fox complained of occasional stress incontinence, urgency incontinence and dyspareunia. A physical exam revealed atrophic vaginitis with no extrusion noted.[25]

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[20] FOXS_URSA_MDR0022-25
[21] FOXS_WPOBG_MDR259-262
[22] FOXS_URSA_MDR0026-29
[23] FOXS_WPOBG_MDR00263-266
[24] FOXS_WPOBG_MDR0269-272

[25] FOXS_URSA_0095-98

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- On May 22, 2015, Mrs. Fox saw Dr. Villa-Olvera for an annual exam. She reported dyspareunia and vaginal dryness without vasomotor symptoms. Her review of symptoms is positive for leaking urine. Her physical exam is unremarkable. There is no atrophy or erosion noted at this visit.[26]

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2002 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

[26] FOXS_WPOBG_MDR00287-291

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- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina, peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

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Safer alternatives designs and procedures existed in 2002 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy. Dr. Haverkorn testified regarding the autologous sling as follows:

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Q. Is the autologous procedure a safe procedure in your mind?
A. I feel like it's safe. It's a gold standard procedure.
Q. Is it an effective procedure in your mind?
A. It -- it has been shown to be effective in the literature.
Q. Do you have an opinion as to whether Ms. Fox will require another surgery, such as an autologous sling, in the future for treatment of her recurrent SUI?
A. It depends on how much it bothers her. So I can't -- I can't make that prediction.
Q. It's up to her?
A. Yes.

Deposition of Rashel Haverkorn, MD at 61:8-22

In 2002, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Ms. Fox was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia. As such, Dr. Warner was unable to warn Ms. Fox of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Fox suffered vaginal sling extrusion, contraction, scar plate formation, and failure of the TVT to incorporate, as a result of the physical properties of the TVT device. These conditions are documented in the medical records.

A. Extrusion.

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Dr. Olvera's records specify an erosion of the "edge" of the TVT near the urethra. Dr. Olvera clarified at her deposition she used the terms "extrusion" and "erosion" interchangeably. Dr. Olvera testified:

95

Q. Okay. I just wanted to clarify that because I think Dr. Haverkorn has testified that she found no erosion when she did the -- when she did the excision when she removed the mesh, that she found no erosion but just extrusion.
A. Yes. I'm just using the terms interchangeably.
Q. But you understand that they mean two different things.
A. Different things, I do.
Q. And so it's your testimony that you -- it was not erosion. That you meant to say it was extrusion.
A. I do.

(Deposition of Michelle Villa-Olvera at 94:23-95:13)

Dr. Olvera testified regarding the exposure of the edge of the TVT: (Pages 58:6 to 59:2)

58

Q. When you say "the edge of the sling" -- it's my understanding these devices look kind of like a piece of tape basically. Is that reasonably accurate?
A. Yes.
Q. When you say "the edge," are you referring to the thin side?
A. I don't know which side it was. Oh, you mean as opposed to the long side of it?
Q. Yeah. If you can hold up a piece of paper --
A. It appeared to be the thin side of it, if that's what you're asking me.
Q. So this right here?
A. That's what it appeared to be.
Q. Okay. Did you feel the mesh on

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23 this visit?
24 A. Yes.

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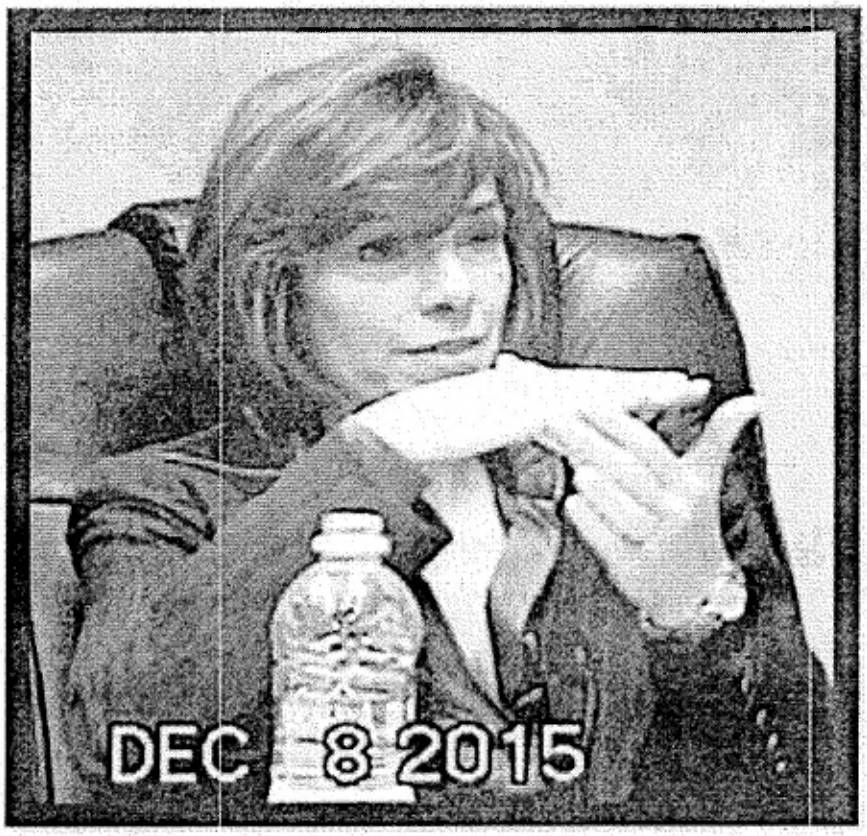
1 Q. What did it feel like?
2 A. Just a firm piece of mesh.

Deposition of Michelle Villa-Olvera at pg 58:6-59:2

Dr. Villa-Olvera indicated the area of the edge extrusion as follows:



Dr. Haverkorn, MD testified regarding Mrs. Fox's extrusion:

25 Q. Is there a difference between an erosion and

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an extrusion?
A. There is.
Q. What is that difference?
A. Erosion would be the mesh inside the lumen of the urethra or the bladder. Extrusion is just exposure of the mesh within the vagina.
Q. And which did Ms. Fox have?
A. She had exposure of the mesh within the vagina, referred to as extrusion.

Deposition of Rashel Haverkorn, MD at 97:25-98:9

I have seen both events of erosion and extrusion of mesh in my clinical practice, including erosion and extrusion events involving the TVT device.

B. Contraction/Shrinkage

Mrs. Fox's TVT contracted post implantation. Dr. Haverkorn testified generally regarding mesh contraction or shrinkage as follows:

Q. What is -- are you familiar with mesh shrinkage?
A. Yes.
Q. Is that what you're talking about here?
A. In some places, yes.
Q. Well, what is mesh shrinkage?
A. It's the shortening or narrowing of the mesh itself.
Q. Now, mesh shrinkage has been described to me a couple different ways. Are you -- when you're saying the mesh shrinks, are you saying that the mesh crumples

22

up like a piece of paper here or that the actual total volume of mesh --
A. I think either would -- either could happen.

Depostion of Rashel Haverkorn, MD at 21:15-22:3

Dr. Haverkorn's explanation report notes the mesh near the right vaginal fornix was "taut." Dr. Haverkorn testified regarding this finding:

rh120715, (Page 40:7 to 40:13)

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40

7 Q. Did you note the mesh in the area of the
8 extrusion around the right vaginal fornix to be taut
9 during your operation?
10 A. That's what it says.
11 Q. And was -- are you referring to the mesh
12 itself as taut?
13 A. Correct.

Deposition of Rashel Haverkorn, MD at 40:7-40:13

Dr. Villa-Olvera testified as follows regarding the TVT:

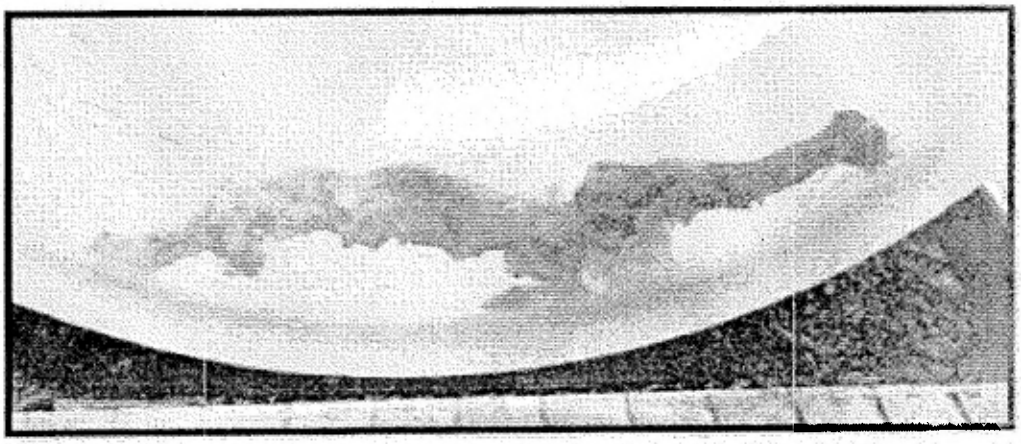
3 Q. Was the mesh loose?
4 A. No.
5 Q. Was it tight?
6 A. It was snugly in place.

Deposition of Michelle Villa-Olvera at 59:3-9

I have observed "taut" pieces of transvaginal mesh in my clinical practice that are the result of post-implantation contraction or shrinkage of the mesh.

C. Scar Plate

The removed portion of TVT was photographed and depicted below:



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This photograph, in my opinion, depicts scar tissue that has become adherent to the TVT as the result of a chronic foreign body response. I have observed such scar plate formation in response to transvaginal mesh in my clinical practice. The post-implantation shrinkage of the mesh involves a combination of two factors: one being the mesh itself contracting and the other being the foreign body response generating a fibrotic response that entails wound contracture.

D. Failure to Incorporate

Portions of the TVT device failed to incorporate into Mrs. Fox's surrounding tissues. Dr. Villa-Olvera testified:

mo120815, (Pages 57:7 to 58:5)

57

when you visualized the mesh, what did it look like?
A. Just a clear, white mesh.
Q. Was there tissue incorporated into the mesh?
A. Not in the mesh that I could see.
Q. Did it look like it had been taken out of the package?
A. Oh, I could not have -- I'm not sure what you're asking.
Q. Could you see the individual pores of the mesh?
A. Yes.
Q. And there was not tissue incorporated into those pores?
A. Not that I could tell.
Q. Did you visualize the edge of

58

the sling?
A. It appeared to me to be the edge of the sling.
Q. And what did it look like?
A. Mesh.

Deposition of Michelle Villa-Olvera, MD at 57:7-58:5

I have observed failure of mesh to incorporate in my clinical practice.

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Case Specific Opinion No. 2

Mrs. Fox's extrusion in 2012 was caused by the physical properties of the TVT – specifically, the mechanically cut edge of the TVT. Recognized causes of sling exposure include: (1) a surgical error in implantation technique; (2) atrophy of the vaginal tissue surrounding the device; and (3) the physical properties of the device post-implantation including, but not limited to, retraction, shrinkage, contraction, fraying, roping and curling.[27]

I am able to rule in the physical properties of the TVT, including the edge of the TVT, based on the discussion set forth in Case Specific Opinion No. 1.

I am able to rule out vaginal atrophy as a cause of Mrs. Fox's extrusion in 2012. Mrs. Fox's annual exams in 2008, 2009, and 2010 do not mention atrophic changes to Mrs. Fox's vaginal tissues. Further, Dr. Olvera's January 2012 exam which diagnosed the "edge" erosion/extrusion, does not note atrophic changes to Mrs. Fox's vaginal tissues. Dr. Haverkorn's March 2012 physical exam also does not note atrophic changes. I acknowledge references to vaginal atrophy in June 2012. However, this could not have contributed to the extrusion earlier in 2012 because the eroded portion of TVT was removed in March 2012. I also acknowledge references to vasomotor symptoms in 2010. An isolated reference to vasomotor symptoms does not equate to vaginal atrophy because vasomotor symptoms frequently occur in the absence of vaginal atrophy.

I am able to rule out surgical error as a cause of Mrs. Fox's extrusion in 2012. Mrs. Fox was implanted with the TVT device on December 5, 2002. Dr. Warner perforated the bladder on the high lateral wall of the right side of the bladder during implantation of the TVT. The tape was backed out and the TVT procedure re-initiated. Dr. Warner tensioned the sling with intraoperative Valsalva. This is a tensioning technique described in the TVT IFU and the Nillson study. Following the implantation, Mrs. Fox had difficulty voiding. After a visit to the emergency room, and postoperative catheterization by Dr. Warner, the symptoms resolved. Mrs. Fox's July 2003 visit with Dr. Olvera notes the SUI had resolved. Dr. Olvera's exam in January 2012 identified the area of erosion as under the right pubis. Dr. Haverkorn's March 8, 2012 physical exam identified the mesh extrusion as to the right side of the urethra. Both of these locations are in anatomically distinct areas from the high lateral wall of the right side of the bladder. Because the extrusion developed in a distinct area from where the bladder perforation occurred, I am able to exclude surgeon error in 2002 as playing a causal role in the development of an erosion in 2012.

---

[27] *See* (Ashok, 2012)

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Further, Dr. Haverkorn testified:

4 Q. And in your "History of Present Illness"
5 section on the first page you -- there's a reference to
6 a bladder perforation in 2002. Do you see that?
7 A. Yes.
8 Q. Would a bladder perforation in 2002 have
9 played any role in the development of an extrusion
10 lateral to the urethra in 2012?
11 A. It's unlikely.

Deposition of Rashel Haverkorn, MD at 32:4-11.

Based on the foregoing, it is my opinion within a reasonable degree of medical and scientific certainty, the sling erosion in 2012 was caused by the mechanically cut edge of the TVT device.

Case Specific Opinion No. 3

Mrs. Fox's vaginal pain and dyspareunia (from July 2011 to March 2012) was caused by her sling extrusion, contraction of the TVT device, and scar plate formation. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury;[28] (7) lichen sclerosis ; (8) vaginal tissue atrophy; (8) pelvic floor dysfunction; and (9) pelvic organ prolapse

I am able to rule in erosion, contraction and scarring as potential causes of Mrs. Fox's vaginal pain and dyspareunia in 2012. These conditions are documented in the medical records of Dr. Olvera and Dr. Haverkorn as set forth above. Further, palpation on exam produced pain in Mrs. Fox. Dr. Villa-Olvera testified:

10 Q. When you touched this area, the
11 edge extrusion, what was Ms. Fox's response
12 to that?
13 A. It was painful.
14 Q. And she verbalized that to you?
15 A. She did.

[28] (Ashok, 2012)

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16 Q. Do you have an opinion on the
17 cause of Ms. Fox's dyspareunia as of this
18 visit?
19 A. Oh, I attributed it to the mesh
20 extrusion.

Deposition of Michelle Villa-Olvera, MD at 59:10-20

Dr. Haverkorn testified:

(Page 30:4 to 30:14)
30
4 Now, you noted tenderness
5 over the extrusion?
6 A. Correct.
7 Q. What does that mean?
8 A. The area where the mesh was exposed in the
9 vagina and the surrounding tissues were -- were tender
10 upon palpation.
11 Q. And did Ms. Fox report pain when you palpated
12 the area of extrusion to you?
13 A. I don't remember the interaction, but that
14 seems to be what was documented here.

Pain produced on palpation on exam enables me to rule in the extrusion, contraction, and scarring as a potential cause of Mrs. Fox's dyspareunia pre-explantation.

I am able to exclude paraurethral banding as a cause of Mrs. Fox's dyspareunia and vaginal pain in 2012 because I have not seen any documentation of paraurethral banding in any of Mrs. Fox's medical records.

I am able to exclude vestibulitis, lichen sclerosis, and Wickham striae as the cause of Mrs. Fox's vaginal pain and dyspareunia in from July 2011 – March 2012. These conditions are documented in Dr. Olvera's medical chart as early as 2004. Additionally, Dr. Owoloabi's records note Wickham striae in May, 2012.

These conditions are documented in anatomically distinct areas from the where Mrs. Fox's vaginal pain is documented in 2012. For example:

- Dr. Olvera's records from March 2004 note vestibulitis to external vagina as set forth below

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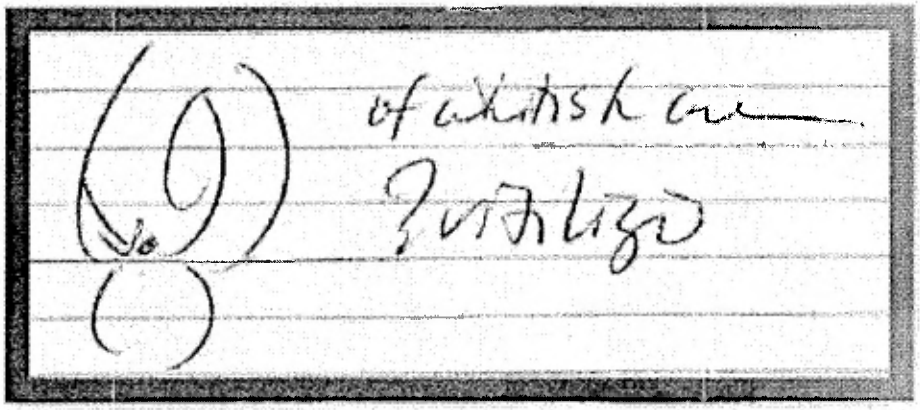
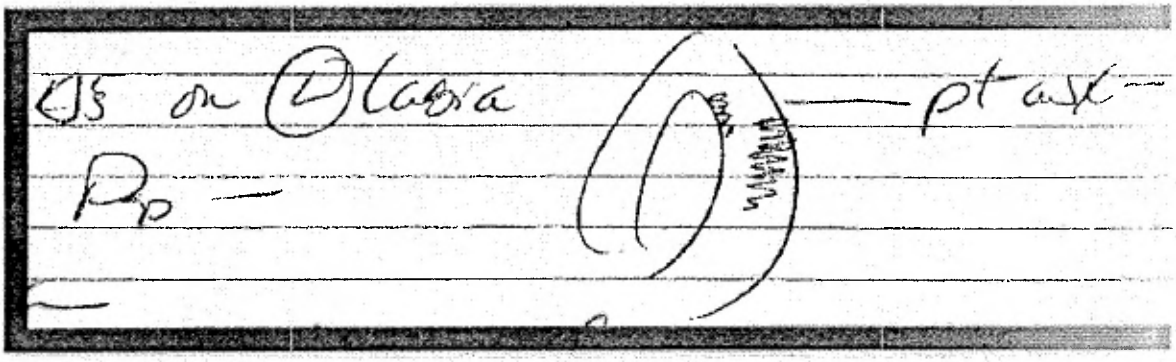
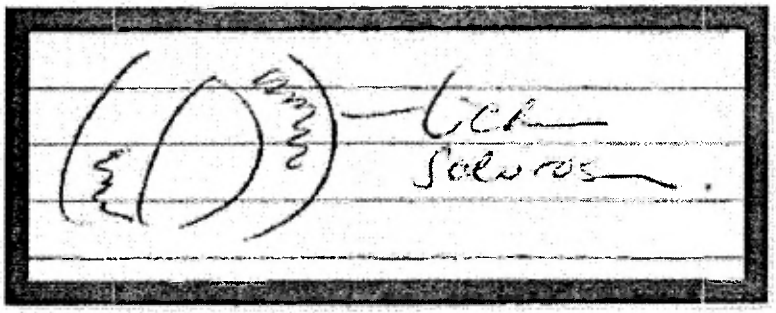


- Dr. Olvera's records from August 2004 note possible lichen sclerosis to the external vagina as set forth below



- Dr. Olvera's records from October 2005 note lichen sclerosis to the external vagina as set forth below:



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- Dr. Owalabi's records from May 2012 note "inflamed and erythematous vestibular structures included the clitoris, labia minora and majora. White reticulate pattern – Wichham striae surrounding inflamed and erosive areas. Progressive introital stenosis."

These conditions are external in nature and can reasonably be excluded as the cause of the internal dyspareunia between July 2011 and March 2012 Mrs. Fox testified was "like a batch of grass burrs."[29] Most notably, these conditions are not documented during the 2011- March 2012 timeframe. Dr. Villa-Olvera testified:

My question was focused on the external genitalia.
A. Okay.
Q. What were your -- what were your findings specific to that area of the anatomy?
A. There were no changes from the prior month.
Q. And there's no active lichen sclerosus noted, correct?
A. It was not noted.
Q. And there's no active vulvalar vestibulitis, correct?
A. Correct.
Q. Are those things that would have been documented had you observed them?
A. Yes.

Deposition of Michelle Villa-Olvera, MD at 55:1-18

Further, Mrs. Fox was asked about her lichen sclerosis and testified the type of pain was different and specified that the pain of lichen sclerosis "is an intense itching."[30] Because the itching pain is of a different nature, and in a different area than the internal dyspareunia between July 2011 and March 2012, lichen sclerosis/vulvular vestibulitis and Wickham striae can reasonably be excluded the cause. These absence of these conditions as active conditions during the July 2011 – March 2012 timeframe enables me to reasonably exclude the etiologies as a cause of Mrs. Fox's dyspareunia at that time.

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[29] Deposition of Sherry Fox at pg 91 ln 10-11
[30] Deposition of Sherry Fox at pg 48 ln 25 – pg 49 ln 1

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Neuromuscular injury is excludable as the cause of Mrs. Fox's dyspareunia between July 2011 and March 2012. Mrs. Fox received a series of injections in early 2009 for lumbar pain. There is no indication this pain radiated into Mrs. Fox's pelvis. Further, the joint block injections appear to have successfully treated Mrs. Fox's back pain. Lumbar issues are excludable as the cause of Mrs. Fox's "sticker burr" dyspareunia between July 2011 and March 2012.

Vaginal tissue atrophy is excludable as the cause of Mrs. Fox's dyspareunia between July 2011 and March 2012 for the reasons set forth in my Case Specific Opinion No. 1.

I am able to exclude pelvic floor dysfunction as the cause of Mrs. Fox's dyspareunia between July 2011 and March 2012. Dr. Villa-Olvera testified regarding her January 27, 2012 visit:

(Pages 51:17 to 52:5)

51

Where was the area of tenderness in relation to the urethra?
A. In the area where the mesh was being extruded.
Q. And what area was that specifically?
A. It was to the right of her urethra.

52

Q. So setting aside the area to the right of Ms. Fox's urethra, did you document any other areas of tenderness at that time?
A. I did not.

Dr. Haverkorn testified regarding her March 8, 2012 visit as follows:

Q. Now, you noted the levators were nontender, correct?
A. Correct.

Deposition of Rashel Haverkorn, MD at 29:2-4

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The absence of documented tenderness to the pelvic floor musculature (other than the area of extrusion) enables me to reasonably exclude pelvic floor dysfunction as a potential cause of Mrs. Fox's dyspareunia between July 2011 – March 2012.

Pelvic organ prolapse can also be ruled out as a cause of Mrs. Fox's dyspareunia as she has no evidence of prolapse during any of her visits to her doctors.

Case Specific Opinion No. 4

Ms. Fox continues to have dyspareunia presently. As part of my expert review and preparation of my opinion regarding Ms. Fox, I performed an independent medical exam of this patient on December 4th, 2015. At that time, the patient reported several bothersome symptoms including voiding dysfunction, vaginal pain, and dyspareunia. Her voiding dysfunction consisted of urinary incontinence, primarily stress urinary incontinence. She also described urgency urinary incontinence, somewhat believed with Vesicare. With regards to her pelvic pain, she described a pain sensation on the outside of her vagina that on physical exam was reproducible on exam in the right side of her vaginal introitus. Additionally, she had reproducible pain on exam in the area of her right vaginal sulcus. In this area, fibrotic scar tissue was noted as well as a more thickened area of tissue towards the supero-lateral apex of the sulcus consistent with palpable mesh deep to the fibrotic tissue. Of note, this is also the location of her dyspareunia, which has been so intense that she has refrained from sexual intercourse because of the pain she has encountered during vaginal penetration.

In considering the causes of her dyspareunia following synthetic sling surgery, I considered a list of differential diagnoses, including: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury; (7) lichen sclerosis; (8) vaginal tissue atrophy; (9) pelvic floor dysfunction; and (10) pelvic organ prolapse. Based on my review of her medical records and my physical exam, I am able to rule in erosion, contraction, and scarring as causes of her dyspareunia. On vaginal bimanual exam, the pain and tenderness she experienced during intimacy was reproduced upon palpation of the anterior vaginal wall in the area of the right vaginal sulcus and right paraurethral area, precisely in and around the area of her mesh erosion and in the area of palpable scar and residual mesh. Although, Mrs. Fox had changes on physical exam consistent with vulvovaginal atrophy, her dyspareunia preceded these as memorialized in her prior medical records from multiple doctors over multiple visits. Moreover her pain during intercourse was located in and around the area of her mesh erosion event. Paraurethral banding was not present on physical exam and can be rules out as a cause Mrs. Fox's dyspareunia. Pelvic organ prolapsed, pelvic floor dysfunction, and neuromuscular dysfunction can be reasonably excluded as causes of dyspareunia as

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he has no evidence of these findings on history and/or exam. Additionally, Mrs. Fox's lichen sclerosis and history of vestibulitis, as previously memorialized is and has been located externally in her genitalia, in an area where she has not experienced pain with intimacy.

Additional significant findings include an elevated post-void residual of 283 milliliters of urine during this evaluation. This signifies that the patient has voiding dysfunction most likely secondary to pelvic floor scarring. As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elastic and compliance of these tissues. As such, when patients present with complications from synthetic mesh slings, they tend to develop a combination of incomplete emptying in addition to urinary incontinence that is often both stress incontinence in combination with urgency urinary incontinence. This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis. Although cessation of this patient's Vesicare could improve her bladder's ability to empty, stopping this medication would most likely worsen the urge incontinence symptoms that she is also suffering from.

Case Specific Opinion No. 5

Ms. Fox future prognosis as it relates to her pelvic pain, dyspareunia, and voiding dysfunction is guarded. Because she has residual pelvic mesh still inside of her body, she will continue to suffer from pelvic pain and dyspareunia. Moreover, she has pelvic tenderness and residual scar tissue in the area where her mesh erosion was treated. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. Moreover, the surgery she has already had performed by Dr. Haverkorn has resulted in residual fibrosis and scarring in the area of her mesh extrusion. I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure.

In as much an autologous fascial sling or other procedures (not involving synthetic mesh) for incontinence might be considered, these would be inappropriate at the current time because of the elevated post-void residuals that Ms. Fox is currently suffering from. Autologous fascial slings are contraindicated in patients with elevated post-void residuals because they are likely to worsen this condition or even create urinary retention. For this reason, Ms. Fox is not a candidate for this type of surgery and is best treated with medical therapy in combination with lifestyle modifications and pelvic floor physiotherapy. Although these interventions should be

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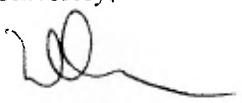
somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, pelvic pain, and dyspareunia will be a lifelong condition for this patient.

These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.

Sincerely,



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